



LAW OFFICES OF  
SYNNESTVEDT & LECHNER  
2600 ARAMARK TOWER  
1101 MARKET STREET  
PHILADELPHIA, PA 19107-2950  
TELEPHONE (215) 923-4466  
FACSIMILE (215) 923-2189  
E-MAIL [synnlech@synnlech.com](mailto:synnlech@synnlech.com)  
[www.synnlech.com](http://www.synnlech.com)

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November 12, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ application of Rene Bruno  
Application No. 09/869,685  
Filed June 29, 2001

Examiner G. Nickol, Ph.D.  
Art Unit 1642  
Confirmation No. 8546

PREDICTIVE METHODS BASED ON APLPHA-1-ACID GLYCOPROTEIN LEVELS  
(Atty. Docket No. P23,565-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, Washington, D.C. 20231, on Tuesday, November 12, 2002.

  
\_\_\_\_\_  
Sara Harvell

Commissioner for Patents  
Washington, D.C. 20231

Reply to Examiner's Requirement for Restriction  
and Species Election, As Set Forth in the Action Dated September 10, 2002

Sir:

In response to the Examiner's Requirement for Restriction, as set forth in the Action dated September 10, 2002, applicant elects hereby to prosecute the claims of Group I, that is, Claims 1 to 5 and newly presented Claim 30. Applicant confirms his right to file a divisional application which includes the non-elected claims (Claims 6 to 29).

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Applicant traverses respectfully the Restriction Requirement.

The Examiner's attention is directed to MPEP §803, which states (emphasis added):

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP §§ 802.01, §§ 806.04, §§ 808.01) or distinct as claimed (see MPEP §§ 806.05 - §§ 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP §§ 803.02, §§ 806.04(a) - §§ 806.04(i), §§ 808.01(a), and §§ 808.02).

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

Applicant submits respectfully that there is not one word in the Examiner's Action as to how or why it would be "a serious burden" for the Examiner to perform a search and examination of the application in its entirety. Accordingly, the Examiner's Requirement is deficient on its face because it does not satisfy an essential criteria for issuance of a proper Requirement for Restriction, as set forth in the MPEP.

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Furthermore, applicant submits respectfully that it would not be a serious burden for the Examiner to search and examine the application in its entirety. All of the claims of the present application share many common elements. All of the claims are method claims and they include at least the following technical features: (1) observing a patient's level of alpha-1-acid glycoprotein (AAG); (2) measuring the level of AAG; and (3) making an assessment or recommendation based upon the level of AAG measured. Because there are so many common elements shared by the claims of Groups I, II, and III, it is asserted that it would not be a serious burden for the Examiner to search and examine the methods of the involved three groups of claims.

In addition, the Examiner has ignored the provision of PCT Rule 13.2 which states that "...the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features" (emphasis added). The claims of Groups I, II, and III contain more than one of the same or corresponding special technical features, as referred to in the preceding paragraph. Thus, the Examiner's Requirement is additionally deficient because it has not taken into account the aforementioned technical features.

In view of the above, applicant requests respectfully that the Examiner withdraw the Restriction Requirement.

The Office Action includes also a Species Election Requirement in which the Examiner has required applicant to elect a single invention to which the claims must be restricted. The Examiner has expressed the view that Claims 3, 4, 8, 9, 16, and

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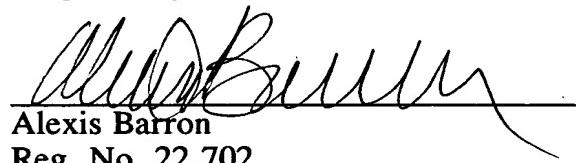
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17 are generic to a plurality of patentably distinct species comprising distinct types of neoplasms.

Applicant elects hereby, as the neoplasm species, non-small cell lung cancer. The claims readable on the elected species are Claims 1 to 5 and newly presented Claim 30.

A favorable action on the merits is requested respectfully. The Commissioner is authorized hereby to charge any additional fees or credit any overpayment associated with this Reply to Deposit Account No. 19-5425. A duplicate of this Reply is enclosed. A Petition for an extension of time to respond to the Action is enclosed also.

Respectfully submitted,

  
Alexis Barron  
Reg. No. 22,702

Synnestvedt & Lechner LLP  
2600 Aramark Tower  
1101 Market Street  
Philadelphia, PA 19107-2950  
Telephone - (215) 923-4466  
Facsimile - (215) 923-2189